Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

# Ionising Radiation (Medical Exposure) Regulations Inspection Report (Announced)

## Breast Test Wales, Llandudno, Public Health Wales

Inspection date: 28 and 29 August 2024
Publication date: 13 December 2024

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Digital ISBN 978-1-83715-028-1

# Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales

## Our purpose

To check that healthcare services are provided in a way which maximises the health and wellbeing of people

## Our values

We place people at the heart of what we do. We are:

- Independent – we are impartial, deciding what work we do and where we do it
- Objective - we are reasoned, fair and evidence driven
- Decisive - we make clear judgements and take action to improve poor standards and highlight the good practice we find
- Inclusive - we value and encourage equality and diversity through our work
- Proportionate - we are agile and we carry out our work where it matters most

## Our goal

To be a trusted voice which influences and drives improvement in healthcare

## Our priorities

- We will focus on the quality of healthcare provided to people and communities as they access, use and move between services.
- We will adapt our approach to ensure we are responsive to emerging risks to patient safety
- We will work collaboratively to drive system and service improvement within healthcare
- We will support and develop our workforce to enable them, and the organisation, to deliver our priorities.

# Contents

# 1. What we did

Full details on how we conduct Ionising Radiation (Medical Exposure) Regulations inspections can be found on our website.

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of Breast Test Wales, Llandudno, Public Health Wales on 28 and 29 August 2024. During our inspection we looked at how the department complied with the Regulations and met the Health and Care Quality Standards.

Our team for the inspection comprised of two HIW Senior Healthcare Inspectors and two Senior Clinical Officers from the Medical Exposures Group (MEG) of the UK Health Security Agency (UKHSA), who acted in an advisory capacity. A Senior Healthcare Inspector led the team.

During the inspection we invited people to complete a questionnaire to tell us about their experience of using the service. We also invited staff to complete a questionnaire to tell us their views on working for the service. A total of 36 questionnaires were completed by clients who have used the service and 10 were completed by staff. Feedback and some of the comments we received appear throughout the report.

Where present, quotes in this publication may have been translated from their original language.

Note the inspection findings relate to the point in time that the inspection was undertaken.

# 2. Summary of inspection

Our inspection found that, although there were positive aspects identified regarding this service and clients were satisfied with their experience at Breast Test Wales, the service was not fully compliant with Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R).

We were not assured that the Employer had fulfilled their duty to provide a framework through written procedures, protocols and quality assurance programmes for duty holders to undertake their functions. Consequently, there was a risk that controls to ensure patient safety might be insufficient, potentially leading to errors or harm. HIW issued an Improvement Notice under Section 21 of Health and Safety at Work etc Act 1974. The Trust has fully engaged with HIW to resolve the issues and as a result of evidence reviewed by HIW, the Improvement Notice was lifted on 10 December 2024. More information and the full Improvement Notice Plan is provided in Appendix B of this report.

## Quality of Patient Experience

Overall summary:
Clients provided positive feedback about their experiences of attending Breast Test Wales, Llandudno. We found staff treated clients with courtesy, respect and kindness. We also found staff provided care in a way that protected and promoted client's rights.

This is what we recommend the service can improve:

- Improve information available to clients on opportunities to feedback using national programmes
- Display "you said, we did" information to show how feedback has been used to improve the service.

This is what the service did well:

- Clients provided positive feedback and comments about the attitude and approach of the staff looking after them
- Commitment to Welsh language information and provision of Welsh language care
- Provision of a wide range of health promotion information.

## Delivery of Safe and Effective Care

Overall summary:
We found some arrangements in place to provide people with safe and effective care. Staff we spoke with were aware of the trust policies and procedures in relation to safeguarding. The setting was clean, tidy and free from clutter. Rooms were modern, well-appointed and equipment was in good working order.

However, we found Breast Test Wales Llandudno was not fully compliant with Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017.

Improvement Notice:
We noted the Employer's Procedures were not comprehensive, ratified or accessible to staff. This meant there was a risk that controls to ensure client safety may be lacking, resulting in potential for error or harm.

The full Improvement Notice Action Plan is provided in Appendix B of this report.

This is what the service did well:

- Commissioning and testing of new equipment
- Quality assurance programme for equipment
- Well maintained, clean, modern and welcoming environment free from obvious hazards to those visiting the setting
- Safeguarding arrangements.

## Quality of Management and Leadership

Overall summary:
We received the completed Self-Assessment Form (SAF) and associated documentation in a timely manner.

The Chief Executive of Public Health Wales is the designated employer under IR(ME)R 2017. The trust was not able to demonstrate a clear structure or lines of reporting and accountability under IR(ME)R during the inspection.

The governance arrangements described in the SAF appeared to have failed in the implementation of IR(ME)R related to policies and procedures.

Improvement Notice:

- Policies, procedures and documentation were not ratified or accessible to staff.
- Insufficient duty holder understanding and knowledge of IR(ME)R 2017
- Insufficient evidence of training and competency for specific practical aspects.

The full Improvement Notice Plan is provided in Appendix B of this report.

This is what we recommend the service can improve:

- Some staff told us that they did not feel involved in decisions made about their work.

This is what the service did well:

- NHS mandatory training compliance
- Appraisal rates for staff
- Understanding of Duty of Candour.

# 3. What we found

# Quality of Patient Experience

## Patient feedback

HIW issued online and paper questionnaires to obtain the views of clients that used this service to complement the HIW inspection in August 2024. In total, we received 36 responses from clients at this setting. Responses were mostly positive across all areas, with all who answered rating the service as 'very good' or 'good.' Not all respondents completed the questionnaire to the end and some questions were skipped throughout. An example comment we received about the service included.

> ***"A great service, hardly had to wait, very professional."***

## Person-centred

### Health promotion

There were bilingual (English and Welsh) posters displayed that provided information to those attending for screening to advise staff if they may be pregnant or breastfeeding. We saw health promotion material displayed in the waiting areas within the department. This included information on the benefits of not smoking, reducing risks of breast cancer, being breast aware etc.

### Dignified and respectful care

There were suitable arrangements in place to promote client privacy. All but one respondent who answered the questionnaire confirmed that:

- Staff treated them with dignity and respect
- Measures were taken to protect their privacy
- They were able to speak to staff about their procedure without being overheard by other patients
- Staff listened to them.

### Individualised care

All but one respondent felt they were involved as much as they wanted to be in decisions about their treatment and that staff explained what they were doing.

Clients we spoke with were also complimentary about their care.

## Timely

**Timely care**
Staff we spoke with explained the arrangements in place for communicating screening appointments.

Clients attended for screening on the second day of our inspection, and no delays to appointments were seen on that day. There was a sign displayed in the waiting area to let staff know if there is a delay to their appointment time.

## Equitable

**Communication and language**
The Welsh language was well promoted within the department. We saw bilingual posters in Welsh and English with information clearly displayed within the department. We saw clear bilingual signage in place to direct visitors to the department. Some staff members told us that they were Welsh speakers and some staff were also learning Welsh.

Staff we spoke with described some of the arrangements in place to help people with hearing difficulties and those whose first language was not English. There was a hearing loop available in the main reception. All staff that we spoke with were aware of how to access translation services if needed to support clients using the service. Staff confirmed that a mobile device was available to support translation for patients whose first language was not English or Welsh.

We saw some information displayed on how to feedback on care including multiple QR codes. Staff members that we spoke with were able to confirm how they would deal with feedback, both positive and negative. We were informed that clients could complain via the NHS Wales Putting Things Right process. However, there was no Putting Things Right poster on display in the department.

There was no information displayed about Llais, the national, independent body set up to give the people of Wales a stronger voice in their health and social care services. There was also no “You said, we did” board or similar displayed to indicate how the service has taken action on any feedback received.

**Breast Test Wales, Llandudno must ensure that the relevant posters are displayed on the following:**

- **Llais**
- **Putting Things Right**

- **You said, we did information.**

**Rights and equality**
We found client rights were protected and promoted in the department. Staff explained the arrangements in place to make the service accessible to all, such as wheelchair access. The department was accessible with wide doors, clear corridors and spacious screening rooms. Breast screening equipment was adjustable to examine those that were unable to stand at breast screening appointments. Staff members confirmed that longer appointments were available for those clients that needed extra support.

We were told that equality and diversity training for all staff was mandatory, and we saw training records that indicated a high level of compliance. All staff we spoke with confirmed they had completed this course online. Staff we spoke with had a good awareness of their responsibilities in protecting and promoting patient rights when attending the department. They were able to confirm the arrangements in place to promote equality and diversity in the organisation.

All staff that answered the HIW survey said they had fair and equal access to workplace opportunities and that the workplace was supportive of equality and diversity.

# Delivery of Safe and Effective Care

## Compliance with The Ionising Radiation (Medical Exposure) Regulations 2017

**Employer's Duties: establishment of general procedures, protocols and quality assurance programmes**

*Procedures and protocols*
Documentation was provided in advance of the inspection as part of the completed Self-Assessment Form (SAF).

We reviewed all IR(ME)R documentation submitted in advance of the inspection and spoke to duty holders and senior management to confirm understanding of processes and practice. Overall, we found that the policies and procedures were:

- lacking formally agreed ratification
- only available to staff in draft / awaiting update format
- lengthy and difficult for staff to locate and follow
- not always easily accessible to duty holders (especially those working on the mobile units)
- not always aligned with clinical practice
- not always reflective of current recommended best practice
- not always read and complied with consistently by all duty holders.

One example regarding ratification processes involved the Radiation Safety Policy which was submitted in advance of the inspection. We noted the review and publication dates were documented as 'TBC' on this submitted policy. A different Radiation Safety Policy was provided to the inspection team during inspection. There were discrepancies between the two documents regarding the groups responsible for approving policies and supporting policies which could not be clarified by the service.

We noted Employer's Procedures were not comprehensive, ratified or accessible to staff. This meant there was a risk that controls to ensure patient safety may be lacking, resulting in potential for error or harm.

**Healthcare Inspectorate Wales (HIW) was not assured that the Employer had fulfilled their duty to provide a framework through written procedures, protocols and quality assurance programmes for duty holders to undertake their functions. HIW issued an Improvement Notice under Section 21 of Health and Safety at Work etc. Act 1974. More information is provided in Appendix B of this report.**

Employer's Procedures that are required under IR(ME)R 2017 were only available in draft form, located within a draft Radiation Safety Procedures document V21. This document was submitted in advance of the inspection and marked as "under review" and dated 7 December 2021.

Employer's Procedures did not provide clear instructions of how and when a process should be carried out and did not always identify who was responsible for carrying out tasks. The Employer's Procedures referred the reader to additional documentation for detail that should have been included in the procedure. The supporting documentation was found to be lengthy and difficult to follow.

Documentation did not accurately reflect the clinical practice within the setting. Staff members that we spoke with were unable to confirm, when questioned, where the Employer's Procedures were available for their reference. This meant they were not always able to confirm the process for carrying out tasks in relation to the IR(ME)R roles. Staff members while working on the mobile mammography units were unable to access the Employer's Procedures due to the lack of internet/intranet access installed on the mobile units.

Specific feedback in relation to individual Employer's Procedures and documentation was shared as part of the review of the SAF during the inspection and highlighted throughout this report. This included detailed suggestions for improvement. **Due to the number of suggestions covered, the Employer is required to act on specific feedback shared in the SAF meeting during the inspection, in relation to the updating of each Employer's Procedure.**

The IR(ME)R documentation reviewed did not routinely include a consistent and systematic process for the review, update and dissemination of changes. In a HIW local review of breast screening services at Breast Test Wales in 2020, there was a recommendation to "*introduce a consistent and systematic process of reviewing and updated and dissemination of changes to processes and policies, this should include the use of version control*". It was disappointing to note that at the time of this inspection, this remained incomplete and this recommendation had not been actioned.

**The quality assurance of policies and procedures was covered in the Improvement Notice issued to Breast Test Wales in relation to compliance with IR(ME)R 2017. More information is included in the Improvement Notice Plan in Appendix B.**

*Referral process and guidelines*

We reviewed the referral process and guidelines as part of the SAF review. This information was limited and there were no referral criteria for screening patients available. There was a lack of clarity from the documentation reviewed and conversations with staff and managers around referral guidelines and processes.

On discussion with the service, clients received an invitation letter which was generated by the National Breast Screening System (NBSS). This invite, which serves as the referral, includes an appointment date and time and is issued by the head of the programme, although the invite letter was not signed by the referrer. The head of programme is entitled as the referrer for screening.

Where a client required an appointment with the assessment clinic or was called for a technical recall, the operator carrying out the clinical evaluation acted as the referrer. On review of the record keeping, there was no evidence of a referral form for this process and therefore no evidence of an identifiable referrer.

**The issues related to referral process and guidelines were covered in the Improvement Notice issued to Breast Test Wales in relation to compliance with IR(ME)R 2017. More information is included in the Improvement Notice Plan in Appendix B of this report.**

**The Employer must review and document the referral process.**

The referral process must be reviewed to include the following:

- a process to provide the referrer with access to established referral guidelines
- evidence of referral guidelines for screening mammography
- a process for document control and record retention of primary source information to support IR(ME)R compliance audits
- evidence of individual referral for biopsy patients and assessment clinic
- a referrer signature on the screening invitation letter.

*Diagnostic reference levels (DRL)*
Staff we spoke with were able to confirm that they were using local diagnostic reference level (LDRL) for screening mammography. DRL charts were displayed on the notice boards in both mammography rooms.

We reviewed the Employer's Procedure for DRLs and noted that it detailed the LDRL for equipment that was no longer in use (Philips MicroDose). The Employer's Procedure did not reference the LDRL for tomosynthesis, that was confirmed by the Medical Physics Experts (MPEs) to be in place and in use. Staff that we spoke with were unaware of the LDRL for tomosynthesis.

**The Employer must update the Employer's Procedure in relation to DRLs to reflect the current DRLs in use. This must include the tomosynthesis DRL.**

*Medical research*
We were told that there were no medical research trials related to exposures involving the department currently.

*Entitlement*
We reviewed the Employer's Procedure for entitlement. This procedure was limited in scope with elements missing.

We reviewed the entitlement records of assistant practitioners, radiographers, advanced practice radiographers, radiologists and clinicians during the inspection. We identified inconsistencies and errors that included:

- the Employer's Procedure lacked the necessary detail to ensure a consistent process for the entitlement of duty holders
- a lack of evidence of a regular review period of entitlement
- a lack of training records or competency assessments provided to underpin entitlement for a breast clinician
- inadequate training records or competency assessments available for equipment quality control (QC) (level A testing)
- a fragmented approach to the entitlement process
- inconsistencies in how duty holders were made aware of their roles and responsibilities under IR(ME)R
- inconsistent documentation review in place for staff to evidence their current entitlement and scope of practice.

We were told that entitlement was reviewed during the annual appraisal. It was highlighted to the service currently there was no evidence that entitlement had been reviewed. The service was advised to establish a system to record when entitlement had been reviewed and make appropriate changes to the entitlement form to capture this.

**The issues related to entitlement were covered in the Improvement Notice issued to Breast Test Wales in relation to compliance with IR(ME)R 2017. More information is included in the Improvement Notice and plan in Appendix B of this report.**

The head of programme at Breast Test Wales entitled the MPEs. There was a competency matrix that was shared with Breast Test Wales. This matrix was used as assurance during the process of entitlement specifically for the MPEs.

*Patient identification*
We reviewed the Employer's Procedure relating to patient identification. This lacked sufficient detail on how identification should be carried out, by whom and

how and where this should be recorded. During the inspection we spoke with operators and asked them to confirm the procedure for patient identification, who completed each element, where the questions were asked and how this information was recorded and retained. Discussions with staff revealed inconsistencies in how each member documented the completion of identification checks.

Due to the lack of detail within the Employer's Procedure, this practical aspect was being carried out in an inconsistent manner. There was no clear process of document retention to support IR(ME)R compliance audits. As a result, the employer cannot ensure written procedures are complied with in relation to patient identification and therefore these processes were not compliant with IR(ME)R 2017.

The Employer is required to update the Employer's Procedure and ensure a robust process is in place for carrying out and recording identification checks. Due to the lack of clarity and detail in the Employer's Procedure, limited documentary evidence available for review and inconsistent processes described HIW issued an Improvement Notice. **The issues related to patient identification were covered in the Improvement Notice issued to Breast Test Wales in relation to compliance with IR(ME)R 2017. More information is included in the Improvement Notice Plan in Appendix B of this report.**

*Individuals of childbearing potential (pregnancy enquiries)*
The evidence provided in the SAF submitted by the setting showed that there was an Employer's Procedure in place for making enquiries of individuals of childbearing potential. We reviewed the procedure and discussed with relevant staff. We noted gaps including the following:

- The procedure did not state what duty holder was responsible for performing pregnancy check for family history, Hodgkin's surveillance
- Clients were also not actively asked if they were breastfeeding, despite the local quality manual stating the potential impact on diagnostic quality
- The procedure did not indicate where these discussions were recorded.

**The Employer must review and update the Employer's Procedure related to individuals of childbearing potential and update it in line with best practice.**

*Communicating Benefits and risks information*
As part of the evaluation of the SAF, it was confirmed that every client invited for routine breast screening received a copy of the NHS Breast Screening leaflet 'Helping You Decide.'

Every client invited for screening within the family history programme received a copy of the Breast Test Wales leaflet 'Breast screening explained.' These leaflets set out the benefits and risks of breast screening, including the risks from radiation.

Most staff that we spoke with confirmed that there was a language line for translation services, if required. The service was currently testing a handheld translation device on the mobile units, which had been well received.

*Clinical evaluation*
We reviewed the SAF and confirmed there were appropriate processes for clinical evaluation. Each set of screening mammograms was double blind read by an approved reader (who may be a Consultant Radiologist, Breast Clinician, Consultant Radiographer or Advanced Practitioner Radiographer). The evaluation was recorded on the breast screening computer system (NBSS). In the case where clients had been recalled by one or both readers, the imaging was reviewed again and consensus reached to establish if the recall should stand. A clinical assessment sheet was completed and filed in the client notes.

Assessment images were evaluated during the assessment clinic and recorded in the clinic notes.

*Non-medical imaging exposures*
The service confirmed they do not carry out non-medical imaging exposures.

**Employer's duties: clinical audit**
The process for clinical audit programme was shared along with examples through the completed SAF. We saw that the clinical audit programme is broadly aligned with the NHS Breast Screening Programme (NHSBSP) standards. The audit programme was informed by the review of the quality assurance data each year. This helped focus on aspects of the service which required further attention. Discussions regarding audit results are captured through the meeting minutes that were reviewed.

Some of the clinical audits reviewed during the inspection were found to be inconsistent in how audit findings were presented and lacked evidence of in-depth analysis of results.

The development of a consistent process for audit and carrying out in-depth analysis will assist staff in closing the feedback loop to drive service improvements.

**The employer must ensure that there is a standardised approach to the reporting of audits, the learning actions to be implemented in the audit results and whether there is a need for reaudit.**

The department did not perform any IR(ME)R compliance audits. Staff confirmed during the inspection that consistent and documented evidence is not routinely retained to support effective audit of IR(ME)R compliance.

**The employer must ensure an appropriate process for retention of IR(ME)R documentation and appropriate IR(ME)R compliance audits are commenced, completed and results and learning disseminated appropriately.**

**Employer's duties: accidental or unintended exposures**
Staff we spoke with were able to describe processes for reporting radiation incidents related to accidental or unintended exposures.

We were told that any radiation incidents were logged on the Datix system and reported to the medical physics team, who would offer advice and confirm if the incident was notifiable to HIW. All learning was shared initially with the individual involved in the incident through an informal conversation and feedback via the Datix system. Senior staff in the department confirmed that all incidents, near misses, compliments and complaints were discussed at staff meetings. Any identified actions required were taken forward independently. It was unclear if the IR(ME)R employer was informed of non-notifiable incidents, near misses or trends.

*There are two separate services in Wales; breast screening and the symptomatic service and the IT systems are separate.*
There was a potential risk of duplicate referrals, where a client would receive an invite for screening, despite being on the symptomatic pathway which would not be documented in the breast screening administrative systems.

The service stated that operators did not have access to previous imaging undertaken by symptomatic service in the Health Board and that they relied on the client providing this information accurately as to mammograms received in the last six months. There was no process in place for checking previous imaging history undertaken by the Health Board if the client was unable to confirm this information. We did not see evidence to confirm that this verbal confirmation was recorded or retained for future reference. **The issues related to previous imaging information were covered in the Improvement Notice issued to Breast Test Wales in relation to compliance with IR(ME)R 2017. More information is included in the Improvement Notice Plan in Appendix B of this report.**

We reviewed evidence that confirmed incidents were brought to the annual meeting of the radiation protection group (RPG). Datix incidents are also discussed at the programme board. At the annual RPG meeting the MPEs presented a summary of incidents that had occurred and listed by theme.

Learning was shared through staff meetings. We were told that anything which required urgent dissemination would be communicated via alternative methods.

During discussions with management, it was noted there was no formal overarching trend analysis reports for incidents and near misses. However, incidents were discussed in minuted meetings.

**The Employer must consider performing trend analysis of incidents and near misses with comparisons to previous time periods to support the service identifying potential trends in incidents and near misses.**

On review of the Radiation Safety Procedures related to accidental and unintended exposures we noted that the guidance was to "*report any incidents involving a (suspected) dose to the patient more than three times the expected amount.*" The service noted that this does not reflect current practice within the organisation. We advised that this is also not in keeping with current Significant Accidental or Unintended Exposures (SAUE) guidance and this required updating.

The wording 'exposure suspected to be greater than intended' is not in keeping with current terminology. The setting was advised to update this in line with SAUE guidance and consider using the term 'significant accidental and unintended exposures.' Furthermore, within the Radiation Safety Procedures, section C9.4 there was reference to the criteria for notification, but this did not provide reference to current SAUE guidance. It advised contacting the MPE.

**Due to the range of concerns highlighted on review of the documentation and processes related to accidental and unintended exposures, the Employer is required to undertake a whole scale review and update of this procedure. The Employer must review and update this Employer's procedure in line with current guidance.**

**Duties of referrer, practitioner and operator**
We reviewed the Employer's Procedure and Radiation Safety Procedure which included the entitlement of referrers, practitioners and operators to carry out their duties. This Employer's Procedure needs to be more robust and include the following:

- how duty holders were made aware of their roles and responsibilities under IR(ME)R
- how training and competencies were assessed and signed off
- how staff evidenced their entitlement and scope of practice
- a review period for entitlement across all duty holders.

Staff, at all levels that we spoke with, were not always aware of their duty holder roles and responsibilities under IR(ME)R and the general understanding of IR(ME)R across all levels was found to be insufficient**. The issues related to duty holder understanding of IR(ME)R were covered in the Improvement Notice issued to Breast Test Wales in relation to compliance with IR(ME)R 2017. More information is included in the Improvement Notice Plan in Appendix B.**

**Justification of individual exposures**
We reviewed the document 'Justification Guidelines' and suggested the setting change the title to 'Authorisation Guidelines' to support staff understanding of authorisation. This document also lacked control measures such as version number and review date.

Our discussions with staff showed there was some confusion around the use and purpose of the authorisation guidelines that were in place.

The SAF described the process for authorisation and how this should be recorded. Where the practitioner had delegated authorisation to the IR(ME)R operator, there was a guideline that detailed the authorisation criteria for the operator. The service stated that authorisation was recorded on the assessment clinic note. During inspection of record keeping, this was found not be to the case and staff could not demonstrate evidence of authorisation.

During staff discussions it became apparent there was a lack of understanding regarding the process for justification and authorisation amongst staff that we spoke with across all staff groups. During the review of record keeping, there was no recorded evidence of justification and authorisation of referrals for screening, assessment clinic and technical recalls. As a result, it was not possible to determine if justification had occurred or identify the duty holder who performed this task. Due to the lack of evidence of authorisation, it was not possible for staff to carry out audits on compliance in this area.

**The Employer must ensure staff have a clear understanding of the process for justification and authorisation. Evidence of authorisation must be recorded and audited to ensure compliance with IR(ME)R.**

**Optimisation**
We were told that practitioners and operators ensured doses were as low as reasonably practical (ALARP) via a number of factors. The SAF confirmed that mammography techniques followed national standards.

The medical physics service performed an annual patient dose surveys to confirm that doses received by the client on each piece of equipment were in line with local and national DRLs.

We reviewed evidence that confirmed a Quality Assurance (QA) programme and planned maintenance were in place to ensure that equipment performance met national standards.

Equipment was commissioned with support from the manufacturer to optimise exposures from the outset. Exposure protocols were displayed in each room to guide operators.

*Carers or comforters*
An Employer's Procedure was in place to provide advice and guidance on exposures to carers and comforters. We reviewed this document and found it did not have sufficient detail, and it did not match clinical practice.

Duty holders we spoke with could not consistently confirm the process for the identification and recording of a carer or comforter exposure. During the inspection it became apparent that clinical practice did not align with the procedures in relation to what was recorded regarding the carer and comforter. In relation to recording details of the carer or comforter, only the relationship to the client was recorded. Therefore, the annual dose constraint for the carer and comforter could not be applied as they could not be retrospectively identified.

**The Employer must review and update the carers and comforters Employer's Procedure to ensure compliance with IR(ME)R and clinical practice.**

**Expert advice**
We confirmed the employer had appointed and entitled a Medical Physics Experts (MPEs) to provide advice on radiation protection matters and compliance with IR(ME)R 2017.

Staff we spoke with said they could access expert advice, when required. It was positive to note the involvement made by the MPEs, who were clearly engaged with the department despite not being on site daily.

We noted that Medical Physics support was good. This was evidenced by their involvement in a range of groups and committees, as well as advising staff when required. MPEs were an integral part of QC testing, procurement and commissioning of equipment at Breast Test Wales. They had also been responsible for the establishment of a local DRL for tomosynthesis.

**Equipment: general duties of the employer**
We reviewed an equipment inventory that indicated that all X-ray equipment used in Breast Test Wales, Llandudno was installed in 2022/2023. This equipment inventory complied with regulatory requirements.

The commissioning and testing of new equipment was described and appropriate forms and processes were reviewed. It was confirmed that medical physics commissioned the equipment. During commissioning, medical physics and radiographers performed consecutive testing over three days. The readings from these tests were used to establish baselines for future quality testing. The baselines are reviewed following installation of a new tube or detector, recalibration or software updates.

Within the equipment QC records, there was a dashboard to identify any failures or gaps in testing. Medical physics reviewed these dashboards on a weekly basis. The support from medical physics in this area was seen as notable good practice.

The service had a handover form, which was a modified version of the Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care (AXREM) form, adjusted to the needs of the service. We reviewed an Employer's Procedure to ensure the quality assurance (QA) programme of equipment was followed. There was good evidence of the QA programme being carried out and documented.

## Safe

**Risk management**
During a tour of the department, we noted there was new equipment and found the environment appeared well maintained, modern and in a good state of repair. It offered a bright, clean, clear and welcoming environment for patients. We did not identify any obvious hazards to the health and safety of patients and other individuals visiting the department.

Signage was clearly displayed to alert patients and visitors not to enter controlled areas where ionising radiation was being used.

**Infection prevention and control (IPC) and decontamination**
We found suitable IPC and decontamination arrangements were in place. All areas accessible by patients were visibly clean and free of clutter. The equipment was also visibly clean and staff described suitable cleaning and decontamination procedures.

Personal protective equipment (PPE) was available within the facility and staff we spoke with confirmed they had access to suitable PPE and this was readily available. We also saw cleaning wipes to decontaminate shared equipment and staff demonstrated a good understanding of their role in this regard.

All patients who completed the questionnaire said that, in their opinion, the department was clean and IPC measures were being followed.

All staff who responded to the questionnaire thought there were appropriate IPC procedures in place, that appropriate PPE was supplied and used, and that the environment allowed for effective infection control. All staff agreed there was an effective cleaning schedule in place.

We reviewed training records that showed that staff had completed mandatory IPC training. Staff we spoke with were aware of their responsibilities in relation to IPC and decontamination.

**Safeguarding of children and safeguarding adults**
Staff we spoke with were aware of the Public Health Wales safeguarding policies and procedures and where to access these. They were also able to describe the actions they would take if they had a safeguarding concern.

We checked a sample of five staff records and these confirmed that the appropriate level of safeguarding training had been completed.

## Effective

**Patient records**
We did not find suitable arrangements in place for the management of records used within the department. Systems, processes and forms reviewed did not support IR(ME)R compliance. **The issues related to referral process and associated record retention were covered in the Improvement Notice issued to Breast Test Wales in relation to compliance with IR(ME)R 2017. More information is included in the Improvement Notice Plan in Appendix B of this report.**

As part of the inspection, we attempted to review client referral records. In some instances, the inspection team were unable to appraise current or past client referral documentation, as the primary source information was not retained under the client's file. Therefore, it would not be possible for the Employer to audit IR(ME)R compliance with systems, processes and forms that were inspected, as the documentation was not available.

The records that were available for review were limited and incomplete. All records we reviewed documented inconsistencies with identification checks. It was not possible from the limited documentation seen, to identify who carried out each aspect of the exposure. The forms and processes in place made client record keeping difficult and confusing for staff to complete. Some staff described additional checks that are performed in advance of the exposure; however, these checks were not detailed in the Employer's Procedures and not recorded in a consistent way on the SASP2 form.

We were informed that Breast Test Wales North Wales had an internal shared drive where assessment forms and letters that are shared with the GP are stored. This was a folder only accessible to the Breast Test Wales service.

Digital Information was  not accessible to staff working on mobile mammography units without sufficient Wi-Fi coverage to access the shared drive or other documentation or procedures stored electronically.

It was confirmed that each Breast Test Wales site had their own shared drive. Upon review and interrogation of the shared drive available to staff at Breast Test Wales Llandudno, it was not possible for staff to search the documentation due to the way it was saved.

**The issues related to availability of Employer's Procedures and other information being readily available to all duty holders were covered in the Improvement Notice issued to Breast Test Wales in relation to compliance with IR(ME)R 2017. More information is included in the Improvement Notice Plan in Appendix B of this report.**

Paper documentation was used throughout the patient journey. Staff we spoke with were unable to confirm retention of documentation processes

**The Employer must review document and clinical information guidance to ensure that patient information is stored and retained in accordance with local policy and the General Data Protections Regulation.**

## Efficient

### Efficient

All staff we spoke with confirmed that systems and processes in place at Breast Test Wales, Llandudno were consistent across the three Breast Test Wales sites and that improvements made to processes and procedures at one site would be reflected in the other sites.

**The Employer must ensure that improvements are consistently implemented throughout Breast Test Wales.**

# Quality of Management and Leadership

## Staff feedback

HIW issued an online questionnaire to obtain staff views on services carried out at Breast Test Wales, Llandudno and their experience of working there. In total, we received 10 responses from staff. Not all respondents completed the questionnaire to the end and questions were skipped throughout.

## Leadership

### Governance and leadership

It was confirmed that the Chief Executive of Public Health Wales was the designated employer under IR(ME)R and had overall responsibility for ensuring the regulations were complied with. Where appropriate, the employer had delegated tasks to other professionals working in the NHS Trust to implement IR(ME)R.

We were provided with details of the organisational structure for both Breast Test Wales and Public Health Wales in the documentation supplied in advance of this inspection.

It was difficult to establish clear lines of reporting and responsibilities under IR(ME)R as the completed SAF indicated that these roles were outlined in the Radiation Safety Policy that was also submitted in advance of the inspection. This document was noted as 'draft', and this draft document was available to staff via their online system.

Senior staff confirmed that formal processes were in place to consider and ratify policies and procedures through the Quality Safety Improvement Committee (QSIC) and that these documents are available to staff. The Chief Executive sat on the QSIC and they were aware of the policy sign off through this committee. Whilst we were told that this process was place, in practice this process appeared to have failed in the implementation of IR(ME)R related to policies and procedures, as they were not ratified through this committee.

**The issues related to the use of policies, procedures and documentation that have not been ratified were covered in the Improvement Notice issued to Breast Test Wales in relation to compliance with IR(ME)R 2017. More information is included in the Improvement Notice Plan in Appendix B of this report.**

## Workforce

**Skilled and enabled workforce**
IR(ME)R duty holders that we spoke with did not have adequate understanding and knowledge of IR(ME)R or how the regulation fully applies in clinical practice. The IR(ME)R framework should provide support for staff and ensure safety for clients. Staff were not always aware of the framework within which they were working.

**The issues related to duty holder understanding and knowledge of IR(ME)R 2017 were covered in the Improvement Notice issued to Breast Test Wales in relation to compliance with IR(ME)R 2017. More information is included in the Improvement Notice Plan in Appendix B of this report.**

In relation to IR(ME)R training, there were insufficient records documenting training and competency for operators regarding the use and testing of equipment. There was no evidence of training records and competency sign off for operators carrying out QC testing on equipment, and no evidence of equipment training for the breast clinician.

**The issues related to training and competency were covered in the Improvement Notice issued to Breast Test Wales in relation to compliance with IR(ME)R 2017. More information is included in the Improvement Notice Plan in Appendix B of this report.**

We reviewed the training programme and training logs for mammographers and confirmed this was in place.

We reviewed training compliance in relation to NHS Trust mandatory training and confirmed training compliance levels of over 80% for the department. There was an appropriate system in place for the monitoring of the training compliance.

All staff that we spoke with and those that completed the questionnaire confirmed that in the last 12 months, they had an appraisal, annual review or development review of their work. Senior staff confirmed that the compliance with appraisals was over 74% and that dates were booked for those who had not completed their appraisal.

All staff we spoke with confirmed that they knew and understood the Duty of Candour. This was also confirmed in the questionnaire where all staff agreed that they knew and understand the Duty of Candour and understood their role in meeting the Duty of Candour standards.

All staff we spoke with, and those that completed the questionnaire, confirmed that they felt that there were enough staff for them to do their job properly and that they were able to meet the conflicting demands on their time at work.

## Culture

**People engagement, feedback and learning**
Feedback from staff we spoke with about the culture in Breast Test Wales was broadly positive. Individual staff members confirmed that Breast Test Wales was a positive place to work in and that the support of their peers and direct line managers was supportive.

All staff we spoke with confirmed that senior staff were approachable and visible. Senior staff confirmed a wide range of processes and meetings in place to disseminate information and updates to staff. These include team meetings, email bulletins and via online applications.

In the staff questionnaire half of those answering indicated that they did not feel involved in deciding on changes introduced that affected their work.

**Breast Test Wales, Llandudno is required to reflect on responses from staff suggesting that they do not feel involved in decision that affect their work and inform HIW of the actions it will take to address this.**

# 4. Next steps

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any immediate concerns regarding patient safety and regulatory compliance where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking
- Appendix C: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

The improvement plans should:

- Clearly state how the findings identified will be addressed
- Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed
- Ensure required evidence against stated actions is provided to HIW within three months of the inspection.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

# Appendix A – Summary of concerns resolved during the inspection

The table below summaries the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

| Immediate concerns Identified | Impact/potential impact on patient care and treatment | How HIW escalated the concern | How the concern was resolved |
|---|---|---|---|
| No immediate concerns were resolved during the inspection | | | |
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# Appendix B – Improvement Notice Plan

## Service: Breast Test Wales, Llandudno

## Date of inspection: 28 and 29 August 2024

The table below includes any immediate non-compliance concerns about patient safety identified during the inspection where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking.

| Improvement needed | | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|---|
| 1. | The Employer is required to provide HIW with specific details about the action taken to ensure that all the Employer's Procedures are:<br>• Revised and updated to ensure that they are reflective of current clinical practice<br>• Agreed and ratified prior to making these readily available to all duty holders<br>• Read and complied by all duty holders.<br><br>**Timescale for completion 23 September 2024** | **Regulation 6 Schedule 2 (1)** | Working group stood up 6 September on receipt of the improvement plan. Daily stand ups put in place.<br><br>Review and updating of the Employer's Procedures started 7 September. Working group has updated the documents in line with the framework: Breast screening: guidance on implementation of Ionising Radiation (Medical Exposure) Regulations (2017) – GOV.UK (www.gov.uk) documentation.<br><br>This has included detail currently included in the Radiation Safety Procedures and the IR(ME)R related process in the current Quality Manual. This documentation are separate documents including overarching Employer's Procedures document and 12 detailed Employer Procedures and contain all of the IR(ME)R related processes in one place.<br><br>This has included improvements to: | SH | Completed by 23 September<br><br>Employer's Procedures document revised and updated to ensure that they are reflective of current clinical practice. These were agreed and ratified on 23 September and sent to all IR(ME)R duty holders on the 23 September. |

| Improvement needed | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| | | • documented timelines for record retention<br>• documented evidence of identification of the individual to be exposed or who had carried out this task<br>• process to document evidence of justification or authorisation records held for retrospective analysis or review<br>• process for evidence of individual referral for biopsy patients or assessment clinic<br>• evidence of referral criteria for screening mammography<br><br>Email has been sent to all Duty Holders on Tuesday 17 September to explain feedback from HIW inspection and requirement for urgent action and that new Employer Procedures will be sent via email on 23 September.<br><br>Staff meeting held in one region to discuss approach and discuss changes to gain feedback to inform development of the documentation.<br><br>Review and update was completed by 23 September.<br><br>• Agreed and ratified prior to making these readily available to all duty holders – completed on 23 September<br><br>To meet timescales for agreed and ratification process the documents were reviewed by | | |

| Improvement needed | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| | | National Director Health Protection and Screening Services and Executive Medical Director and Chief Executive and after taking on board changes, approved on Monday 23 September by Chief Executive and employer under IR(ME)R.<br><br>• Read and complied by all duty holders- 23 September<br><br>To meet timescales Employer Procedures were sent out via email on Monday 23 September to all duty holders and request confirmation of receipt and have read the documents by 27 September. This will be followed up promptly for staff on leave and if staff have not yet confirmed receipt. Paper copies made available on mobiles and in static sites across Wales. Duty holders have been asked to feedback any questions or comments on the documents to their line manager which will be collated centrally to inform any revisions.<br><br>Staff training meetings are taking place across the regions from 24 September to 9 October to ensure consistency of messaging and checking understanding of revised procedures and process changes to enable safe implementation. This will be delivered by Radiography Managers to their regional teams. This will include refresher training on IR(ME)R regulations, staff roles under the regulation for duty holders and how to access procedures and relevant information. This | | |

| Improvement needed | | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|---|
| | | | will also include an informal assessment to check staff understanding of the regulations and their application in their role as duty holders under IR(ME)R.<br><br>This action is links to the action under Improvement 7 and will allow opportunity to discuss these in team meetings and that will ensure consistency of messaging and checking understanding of revised procedures and process changes to enable safe implementation. | | |
| 2. | The Employer is required to provide HIW with specific details regarding the review of policies and procedures, this must include quality control measures.<br><br>**Timescale for completion 23 September 2024** | **Regulation 6 (5) (b) Schedule 2(1)(d)** | This detail is included in the reviewed and updated Employer's Procedures (EP1) so the process is clear and can be audited<br><br>This has included improvements in:<br>• documented quality assurance and ratification processes<br><br>. | SH | Completed by 23 September |
| 3. | The Employer is required to provide HIW with assurance that the referral process is compliant with IR(ME)R.<br><br>**Timescale for completion 23 September 2024** | **Regulation 6 (5) (a) Regulation 10(5)** | Action completed in the review and updated Employer Procedures<br>This has included improvements to:<br>• documented timelines for record retention<br>• documented evidence of identification of the individual to be exposed or who had carried out this task | SH | Completed by 23 September except for the digital changes which will be completed by end of October to ensure implemented safely. |

| Improvement needed | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| | | • evidence of justification or authorisation records held for retrospective analysis or review<br>• evidence of individual referral for biopsy patients or assessment clinic<br>• evidence of referral criteria for screening mammography<br><br>This requires changes on the IT system (NBSS) and the SASP2 form. Changes made to process for recording identification check; pregnancy and breast feeding check; and changes to terminology from mammographer to IR(ME)R operator. These changes were agreed 10 September by working group and requested to digital team on 11 September. Digital team agreed to prioritise on 11 September and have implemented changes to the SASP2 form by 23 September.<br><br>Digital implementation will be by end of October as checks are required on the IT system to ensure change is safely implemented, this includes changes that are needed to daybook for implementation on NBSS on the mobiles.<br><br>Until the IT system is fully implemented the SASP2 form will capture the information and this will be retained in line with procedure. | | |

| Improvement needed | | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|---|
| 4. | The Employer is required to provide HIW with specific details about the action taken to ensure that Governance arrangements are in place and robust for this service.<br><br>**Timescale for completion**<br>**4 November 2024** | Regulation 6 | The reviewed and updated Employer Procedures have been approved by CEO as Employer under IR(ME)R.<br>These will be shared with Radiation Protection Group, Breast Test Wales Programme Board (completed 25 September); Senior Management Team Screening Division (1 October) and Directorate Management Team.<br><br>The review date for this first version of the documentation is March 2025 to ensure an earlier review process to check that these are working well or if any feedback for review or changes.<br><br>When the documents are reviewed in the future this will come through the following governance process:<br><br>• Standard review process:<br><br>All IR(ME)R employer procedures and protocols will be reviewed every 2 years by the Radiography Managers, Head of Programme and the Medical Physics Expert (MPE). A standard item on the Medical Physics Group and Radiation Protection group will be to identify which procedures and protocols will be reviewed in the following yearly cycle. The reviewed procedures and protocols will be considered and approved at the Radiation Protection Group. | SH | On plan to meet timescales.<br>Staff meetings planned from 24 September to 9 October to run sessions on updated procedures. Review and audit of implementation by 4 November |

| Improvement needed | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| | | The reviewed procedures and protocols will then be considered and approved by Breast Test Wales Programme Board. These will be the escalated to the Screening Division Senior Management Team chaired by the Director of Screening and then the Directorate Management Team chaired by National Director Health Protection and Screening Services and Executive Medical Director. The reviewed procedures and protocols will then escalate to the CEO for final approval in their role of IR(ME)R Employer.<br><br>• Legislation changes outside of the standard review schedule:<br><br>The Medical Physics Expert will inform the chair of the Radiation Protection Group of any changes in IR(ME)R legislation and guidance which will require a review of the procedures or protocols more promptly than the planned scheduled review.<br><br>The Head of Programme will inform the chair of the Radiation Protection Group of any learning or updated guidance from other UK country Breast Screening Programme which may prompt a review of the procedures of | | |

| Improvement needed | | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|---|
| | | | protocols more promptly than the planned scheduled review.<br><br>Reviews will also take place as necessary following staff feedback, changes in equipment or new techniques, or learning from incidents.<br><br>Staff meeting are planned from 24 September to 9 October on updated procedures to ensure understanding and consistent practice and enable opportunity for feedback from staff and review of the Employer Procedures in practice.<br><br>Audit plan developed and implemented to check compliance across pathway by duty holders to be completed by 4 November. | | |
| **5.** | The Employer is required to provide HIW with evidence of up to date records for all relevant training undertaken by operators in regard to adequate training and competency for use of equipment and testing.<br><br>**Timescale for completion 23 September 2024** | **Regulation 6 (3) (b) Regulation 17 (4) Schedule 3** | This has been actioned and includes improvements to<br><br>• evidence of training records and competency for operators carrying out Quality Control testing on equipment<br>• evidence of equipment training for breast clinician | DP | Completed by 23 September |
| **6.** | The Employer is required to provide HIW with evidence of a | **Regulation 6 (1) Schedule 2 (1) (b)** | Action has been completed in the review and updated Employer Procedures by 23 September . | SH | Completed by 23 September. Employer's |

| Improvement needed | | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|---|
| | robust documented process for the review of entitlement of duty holders.<br><br>**Timescale for completion 23 September 2024** | | This has included improvement to<br>• evidence of regular review of entitlement<br><br>The Regional Radiography Managers hold the entitlement and competency records documenting IR(ME)R duty holders. Training and competency records will be held for individuals and also in an overall spreadsheet detailing a competency matrix. These are to be reviewed annually or more frequently if there are changes to entitlement. | | Procedures document revised and updated to ensure that they are reflective of current clinical practice. |
| **7.** | The Employer is required to provide HIW with assurance of adequate understanding and knowledge of IR(ME)R by duty holders to carry out their duties.<br><br>**Timescale for completion 7 October 2024** | **Regulation 6 (2), regulation 6 (3) (b) & Schedule 3** | Action will be completed in the review and updated of the Employer Procedures and sharing the agreed and ratified documents with duty holders.<br><br>Staff training meetings have been planned across the regions from 24 September to 9 October and that will ensure consistency of messaging and checking understanding of revised procedures and process changes to enable safe implementation.<br><br>The training will be undertaken by the Regional Managers with their direct team and this will cover all IR(ME)R duty holders and there will be follow up for staff on leave. This will include refresher training on IR(ME)R regulations, informed by MPE , staff roles under the regulation for duty holders, detailed review and | DP | Regional training staff meetings planned from 24 September to 9 October.<br>Timescales for completion 9 October (due to planned staff meeting arranged around clinics) |

| Improvement needed | | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|---|
| | | | explanation of the overarching Employer's Procedures document and 12 detailed Employer Procedures and how to access procedures and relevant information. An informal assessment will be undertaken by staff to check their understanding following the training. The aim of the sessions will be that IR(ME)R duty holders understand the IR(ME)R framework and how they apply this in their role in Breast Screening.<br><br>Annual update training will be put in place and discussing this with our colleagues in RPS to cover update training to all duty holders in BTW to cover<br>• Current / updates to legislation<br>• Responsibilities of duty holders<br>• Employer procedures | | |
| **8.** | The Employer is required to provide HIW with assurance that measures are in place to allow for the review of previous diagnostic information or medical records prior to the justification of the exposure.<br><br>**Timescale for completion 23 September 2024** | **Regulation 10 (5) Regulation 11(4)** | Assurance that measures to allow for the review of previous diagnostic information or medical records prior to the justification of the exposure is in place for screening mammograms. The revised and updated Employer Procedures ensure they are reflective of current clinical practice in line with the timescales.<br><br>Improvement have been made on<br>• documented timelines for record retention<br>• documented evidence of identification of the individual to be exposed or who had carried out this task | SH | Employer's Procedures document revised and updated to ensure that they are reflective of current clinical practice. Completed.<br><br>To mitigate further against the risk of a screening participant having a mammogram within 6 months of a previous symptomatic |

| Improvement needed | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| | | • evidence of justification or authorisation records held for retrospective analysis or review<br>• evidence of individual referral for biopsy patients or assessment clinic<br>• evidence of referral criteria for screening mammography<br><br>The SASP2 form details the last screening mammogram and the IR(ME)R Operator checks the date of the last screening mammogram is not within last 6 months. If the mammogram is a technical recall then this is likely to be within the last 6 months.<br><br>The review of previous diagnosis information of medical records prior to the justification of the exposure is not currently feasible for mammograms that have been undertaken in the symptomatic service in the Health Boards in Wales.<br><br>In the guidance document n Breast screening: guidance on implementation of Ionising Radiation (Medical Exposure) Regulations (2017) - GOV.UK (www.gov.uk):<br><br>*The referral process for breast screening is different to an individual imaging referral requested by a healthcare professional. Women are invited for screening if they meet the referral criteria in accordance with the national service* | | mammogram the process around checks will be reviewed and strengthened taking into account the guidance above.<br><br>This will include reaching out to other breast screening programme in UK to explore their processes to mitigate this risk (in process); discussing the access to Health Board PACs system that breast screening doesn't current have ability to access; exploring if can systematically put in place a process if woman is unsure of date of previous symptomatic mammogram for staff on mobile to phone BTW staff to request them to check with either Health Board or on PACs if available. |

| Improvement needed | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| | | *specification. The screening invitation letter must be issued/signed by a registered healthcare professional, entitled by the employer as a referrer.*<br><br>*Each breast screening service must have referral guidelines which outline the set criteria by which a woman is eligible for breast screening and should also include clear processes for dealing with exceptions.*<br><br>*A mammogram may be performed for routine invitations when:*<br><br>• *the woman is registered with a GP practice*<br>• *the woman is aged between 50 and up to 71 birthday*<br>• *a minimum of 6 months has elapsed since a previous mammogram*<br>• *the woman has not had a bi-lateral mastectomy*<br><br>*The mammographer carrying out the examination will ask the woman when and where they had their last mammogram, and if known, the date and discussion must be documented. Verbal confirmation is sufficient and does not routinely require further checks. If the time since last mammogram is greater than* | | This will be undertaken by 4 November in line with Improvement Action 4 |

| Improvement needed | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| | | *6 months, the mammographer will continue with the breast screening examination.*<br><br>This is in line with current practice in Breast Test Wales. This detail has been included in the review and updating of the overarching Employer's Procedures document and the detailed Employer Procedures.<br><br>It is currently not possible to introduce checks on symptomatic mammogram information for the breast screening service in Wales as the services is currently not able to access all of the Health Board PACs systems and Screening Mobiles do not have network connectivity.<br><br>Work to understand how these issues can be addressed will include<br>• Exploring how access to all Welsh Health Board PACs systems. Implementation of new PACS system across Wales is currently planned. PHW implementation is expected by March 2025 with full implementation roll out across Wales expected to take a further 2 years. Understanding how this initiative could be used to address the issue is a priority area.<br>• Secure IT connection to mobiles – technical solution that is cyber secure and feasible – signal issues in some sites in Wales. | | |

| Improvement needed | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| | | • Procurement and resources for secure IT connection<br>• Information Governance approval processes to allow staff to have justified reason to access information as this will be on individual basis<br>• Feasible process to ensure checking information work within running of the screening clinic and does not introduce delays to participants.<br><br>Work to explore and scope this solution can be taken forward but this will need to align to timescales as detailed above.<br><br>To mitigate against the risk of a screening participant having a mammogram within 6 months of a previous symptomatic mammogram the IR(ME)R Operator will ask the woman if she has had a mammogram previously and if so when this was. This will be documented on the SASP2 form and on the NBSS IT system when changes implemented.<br><br>If woman is unsure of date of previous symptomatic mammogram then the mammogram will not be undertaken until the date has been confirmed.<br><br>To mitigate against the risk of a screening participant having a mammogram within 6 months of a previous symptomatic mammogram the | | |

| Improvement needed | Standard/ Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| | | process around checks will be reviewed and strengthened taking into account the guidance above.<br><br>This will include reaching out to other breast screening programme in UK to explore their processes to mitigate this risk; discussing the access to Health Board PACs system that breast screening doesn't current have ability to access; exploring if can systematically put in place a process if women is unsure of date of previous symptomatic mammogram for staff on mobile to phone BTW staff to request them to check with either Health Board or on PACs if available. | | |

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

**Service representative:** 

**Name (print):** **Dr Sharon Hillier**

**Job role:** **Director of Screening Division, Public Health Wales**

**Date: 27/09/24**

# Appendix C - Improvement plan

## Service: Breast Test Wales

## Date of inspection: 28 and 29 August 2024

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

| Risk/finding/issue | | Improvement needed | Standard / Regulation | Service action | Responsible officer | Timescale |
|---|---|---|---|---|---|---|
| 1. | **Some QR codes were seen for people to feedback, however there was not specific information related to Llais (patient experience) or NHS Wales Putting things right. There was also no information on what improvements / changes have been made as a result of feedback.** | **The Employer must, ensure that the relevant posters are displayed on the following:**<br>• **Llais**<br>• **"Putting things right"**<br>• **You said, we did information.** | **Person Centred** | 'Putting things right posters' are already displayed across mobiles and static sites.<br><br>The service will ensure there are posters displayed on the mobiles and static sites on Llais; and information on improvements that have been made as result of feedback | Regional Radiology Managers | To be completed within one month |

| | | | | | | |
|---|---|---|---|---|---|---|
| **2.** | **DRLs that were reviewed did not reference current DRLs in use.** | **The Employer must update the Employer's Procedure in relation to DRLs and LDRLs to reflect the current DRLs in use. This must include the tomosynthesis DRL.** | Regulation 6 Schedule 5 (c) | Employer's Procedures document have been revised and updated.<br><br>The specific document is: Breast Test Wales Employer Procedure 7 (EP7). Procedure to use and review the diagnostic reference levels.<br><br>This includes tomosynthesis DRL. | Completed | This action is completed<br><br>These were agreed and ratified on 23 September and sent to all IR(ME)R duty holders on the 23 September. |
| **3.** | **The Employer's Procedure related to individuals of childbearing potential was not in line with best practice and did not match clinical practice.** | **The Employer must review and update the Employer's Procedure related to individuals of childbearing potential and update it in line with best practice.** | Regulation 6 Schedule 8 | Employer's Procedures document have been revised and updated.<br><br>The specific document is: Breast Test Wales Employer Procedure 4 (EP4). Procedure to establish if a participant of childbearing potential is pregnant or breastfeeding | Completed | This action is completed<br><br>These were agreed and ratified on 23 September and sent to all IR(ME)R duty holders on the 23 September. |
| **4.** | **Some of the clinical audits reviewed during the** | **The employer must ensure that there is a standardised approach to** | Regulation 7 | The audits will be in line with the PHW policy and templates. | This action is in place | This action is in place |

| | | | | | | |
|---|---|---|---|---|---|---|
| | **inspection were found to be inconsistent in how audit findings were presented and lacked evidence of in-depth analysis of results.** | **the reporting of audits, the learning actions to be implemented in the audit results and whether there is a need for reaudit.** | | https://phw.nhs.wales/about-us/policies-and-procedures/policies-and-procedures-documents/clinical-governance-and-infection-control-policies/quality-and-clinical-audit-procedure/<br><br>This has already been actioned for the audits undertaken relating to the implementation of the revised and updated Employer Procedures | | |
| **5.** | **The related CSAUE and SAUE (accidental and unintended exposures) incidents was not in line with current guidance** | **Employer is required to undertake a whole scale review and update of this procedure. The Employer must review and update this Employer procedure in line with current guidance.** | Regulation 8 | Employer's Procedures document have been revised and updated.<br><br>The specific document is: Breast Test Wales Employer Procedure 11 (EP11). Procedure to follow for a significant accidental or unintended exposure. | Completed | This action is completed<br><br>These were agreed and ratified on 23 September and sent to all IR(ME)R duty holders on the 23 September. |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | **The Employer should consider performing trend analysis of incidents and near misses with comparisons to previous time periods to support the service identifying potential trends in incidents and near misses.** | Regulation 8 | This will be taken forward and trend analysis of Datix incidents related to IR(ME)R regulations will be undertaken for the programme<br><br>All incidents are reviewed at the minuted technical assurance meetings and the Radiation Protection Committee. This will now include near misses.<br><br>Clarification on what would be considered as a trend from HIW perspective would be helpful if this can be provided. | Regional Radiography managers working with RPS colleagues and colleagues in integrated governance in the nursing, quality and integrated governance (NQIG) directorate. | This action to be completed within 3 months |
| | **There was a lack of understanding regarding the process for justification and authorisation amongst staff that we spoke with** | **The Employer must ensure staff have a clear understanding of the process for justification and authorisation. Evidence of authorisation must be recorded and** | Regulation 11 Schedule (1) (b) | Employer's Procedures document have been revised and updated.<br><br>The specific document is: Breast Test Wales Employer Procedure 2(EP2). Procedure to identify individuals entitled to act as IR(ME)R | Completed | Completed |

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| **across all staff groups. During the review of record keeping, there was no recorded evidence of justification and authorisation of referrals for screening, assessment clinic and technical recalls.** | **audited to ensure compliance with IR(ME)R.** | | Referrer, Practitioner and Operator for exposures<br><br>This required changes on the IT system (NBSS) and the SASP2 form. Changes have been made to process for recording identification check; pregnancy and breast feeding check; and changes to terminology from mammographer to IR(ME)R operator. These changes have been made to the paper copy of the SASP2 form and the IT changes have been made and implemented on the static sites. Digital work is in progress and this is required before the IT changes are in place on the mobiles.<br><br>Detailed work instructions have also been developed which are aligned with the Employer Procedures and provide the detailed process for staff to follow. | | |

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| | | | | The specific work instruction is Breast Test Wales Work Instruction 7 (WI 7) Performing Screening Mammograms. | | |
| 6. | **We confirmed that current or past patient referral documentation, as the primary source information was not retained under the client's file. Staff were unable to confirm processes in relation to the retention of information storage and retention. Historic mammography film files were stored in an outbuilding which was also used for staff and clinical meetings. It was not clear what the plans** | **The Employer must review document and clinical information guidance and ensure that patient information is retained, stored and destroyed appropriately and in accordance with the General Data Protections Regulation**. | Regulation (10) Schedule 5 | The referral document is retained as the paper SASP2 are completed, retained and then scanned. Once the IT changes are fully implemented for the mobiles then this information will be retained on the IT system.<br><br>The films are stored in line with the retention guidance and they are culled appropriately.<br><br>We will ensure the partition in the space is drawn and locked to address this. | Regional Radiography Managers working with Digital colleagues<br><br>Regional Radiography Manager | Implementation of the IT changes for the mobiles expected by the end of the calendar year |

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| | **were for storage of these films and it appeared inappropriate to store these documents with access to staff that attended meetings there.** | | | | | |
| **7.** | **During the inspection it was confirmed that processes in place at Breast Test Wales, Llandudno were also in place across other sites of Breast Test Wales.** | **The Employer must ensure that improvements required are consistently implemented throughout Breast Test Wales.** | Regulation 6 | All of the actions completed have been completed across the three regions in Wales. | Completed | Completed |
| **8.** | **Individual Employer's Procedures and documentation was shared as part of the review of the SAF during the inspection and** | **Due to the number of suggestions covered, the Employer is required to act on specific feedback shared in the SAF meeting during the inspection, in relation to** | Regulation 6 Schedule 2 (1) | Review and updating of the Employer's Procedures has been undertaken. This is in line with Breast screening: guidance on implementation of Ionising Radiation (Medical Exposure) Regulations (2017) - GOV.UK (www.gov.uk) documentation. | Completed | Completed |

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| | **highlighted throughout this report. Detailed feedback was given during inspection.** | **the updating of each Employer's Procedure.** | | The documentation are separate documents including overarching Employer's Procedures document and 12 detailed Employer Procedures and contain all of the IR(ME)R related processes in one place.<br><br>This has included improvements to:<br>• documented timelines for record retention<br>• documented evidence of identification of the individual to be exposed or who had carried out this task<br>• process to document evidence of justification or authorisation records held for retrospective analysis or review<br>• process for evidence of individual referral for biopsy patients or assessment clinic | | |

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| | | | | • evidence of referral criteria for screening mammography<br><br>Employer Procedures were sent out via email on Monday 23 September to all duty holders and request confirmation of receipt and have read the documents.<br><br>Paper copies made available on mobiles and in static sites across Wales. Duty holders were asked to feedback any questions or comments on the documents to their line manager which would be collated centrally to inform any revisions.<br><br>Staff training meetings took place across the regions from 24 September to 9 October to ensure consistency of messaging and checking understanding of revised procedures and process changes to enable safe implementation. This was delivered by Radiography | | |

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| | | | | Managers to their regional teams. This included refresher training on IR(ME)R regulations, staff roles under the regulation for duty holders and how to access procedures and relevant information.<br><br>Additional training sessions have taken place (29 October and 4 November) for staff who were not able to attend the previous sessions.<br><br>Detailed work instructions have also been developed which are aligned with the Employer Procedures and provide the detailed process for staff to follow.<br><br>Audit plan developed and implemented to check compliance across pathway by IR(ME)R duty holders | | |
| **9.** | **Responses from the staff survey, indicated that staff did not feel involved in decision making.** | **Breast Test Wales, Llandudno is required to reflect on responses from staff suggesting that they do not feel involved in** | Effective | We will reflect on this feedback and consider this with other methods of feedback that have undertaken including the staff survey at organisation | Head of Programme | Identify actions and take forward within 3 months. |

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| | | **decision that affect their work and inform HIW of the actions it will take to address this.** | | level which has shared results recently and will take forward to improve. | | |
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The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

**Service representative**

**Name (print):** **Dr Sharon Hillier**

**Job role:** **Director of Screening Division, Public Health Wales**

**Date:** **08/11/2024**